

DRAFT - January 26, 1989

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

DRAFT STATEMENT CONCERNING INGREDIENTS
FOR USE BEFORE A CONGRESSIONAL COMMITTEE

I am appearing before you today on behalf of the six major American cigarette manufacturers to discuss the use of ingredients that are added to tobacco in the manufacture of cigarettes. I will briefly explain the tobacco industry's record of cooperation with the federal government concerning ingredients, and will then describe the ways in which ingredients are used and the information available concerning the safety of ingredients.

Background

In recent years, the major American cigarette manufacturers have regularly cooperated with the Federal Government concerning ingredients. For example, in 1982, representatives of the Office on Smoking and Health of the Department of Health and Human Services ("HHS") reviewed a list of the most commonly used ingredients that was voluntarily provided by the cigarette manufacturers under an agreement with Dr. Edward N. Brandt, Jr., then Assistant Secretary for Health at HHS. The manufacturers informed HHS at the time that they were prepared to work with HHS as it reviewed the list, but HHS did not communicate with the industry regarding any review undertaken by the agency.

In 1984, the Comprehensive Smoking Education Act was passed. The Act mandated the periodic submission to HHS of

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lists of ingredients, and the cigarette manufacturers have complied fully with the requirements of the Act. In April 1986 the manufacturers submitted a comprehensive ingredient list to HHS pursuant to the Act, and since that time they have submitted an updated list each December. In submitting each of these lists, the manufacturers informed HHS that industry representatives were available to consult with HHS about the ingredients on the list, and to participate in the review of ingredients by HHS.

Despite the industry's willingness to participate, HHS never invited the industry to assist in a review of ingredients. Rather, HHS prepared its report without the assistance of the industry scientists who are most knowledgeable about the use of ingredients. This failure resulted in a report that, we respectfully submit, is inaccurate.

Uses of Ingredients

Ingredients are used for a number of purposes in the manufacture of cigarettes. Some ingredients aid in processing tobacco in the initial stages of cigarette manufacture. Such ingredients increase the efficiency and yield of processing operations but remain in the final cigarette in extremely small and often undetectable amounts. Other ingredients are used as casing materials or humectants. Casing materials help to smooth the taste of cigarettes, while humectants keep the tobacco in cigarettes moist. Finally, many of the ingredients on the lists that have been submitted to HHS are used to give

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individual brands of cigarettes their distinctive flavor and aroma.

The use of ingredients in cigarettes is not new. Most of the principal processing aids, casing materials, and humectants, for example, have been in use for decades. Many of the major flavoring agents also have been in use for an extended period. Particular flavoring ingredients are added or eliminated from time to time as new products are introduced or existing products are reformulated in response to changing consumer preferences.

The lists of ingredients that have been submitted by the industry to HHS contain many compounds, but about 20 of the ingredients comprise approximately 99% of the total amount, by weight, of ingredients used by the industry. Most other ingredients are used in much smaller amounts, in many cases only as components of flavor formulations purchased from independent flavor manufacturers. These flavor manufacturers often use a large number of ingredients in a particular flavor, but typical industry-wide usage of most of the ingredients found in these flavors is under 10 pounds per year.

In addition, while a large number of ingredients are used, it is important to note that ingredients do not comprise a significant portion of the final cigarette. For example, processing aids, which typically are used in large amounts, generally disappear during the manufacturing process. The

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residual amounts of such processing aids in the final cigarette are small and often undetectable.

Similarly, as noted above, a large number of the ingredients are used as flavors, but these substances typically appear in the final cigarette in minuscule amounts. Flavor ingredients will normally constitute less than one-tenth of one percent by weight of the final product, and all ingredients, including casing materials, humectants, and the few major flavors, will typically comprise no more than 5% by weight of the cigarette.

Data on Ingredients

The key question of interest to this Committee is, of course, the safety of the ingredients being used. Contrary to the HHS report, it is our view that these ingredients as used in cigarettes do not present a hazard. HHS appears simply to have failed to consider the evidence that supports this view.

In considering the safety of a specific ingredient, several obvious questions arise. Is it carcinogenic? Is it mutagenic? Is it a teratogen? Is it approved for use in cigarettes, or in other consumer products? How is it used in cigarettes, and does it appear in the final cigarette?

None of the ingredients used by the companies for which I am appearing has been determined to be a carcinogen. This does not mean that questions have not been raised from time to time with respect to specific ingredients. Every scientist knows that from time to time questions will be

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raised about the safety of particular substances. Where such questions have been raised, they have been answered with a determination that the substance is not carcinogenic.

In addition, I do not believe that any of the ingredients are mutagenic or teratogenic. A few of them may have tested positive in isolated mutagenicity screening tests. Where this is the case, more extensive research has generally shown that the compound is not mutagenic. None of the compounds is recognized as a teratogen, because none has shown positive test results in two species, the standard for determining teratogenicity.

Most of the ingredients are used in a wide variety of consumer products. For example, most of them have been reviewed by FDA, and are specifically approved for use in foods. Many are also approved by other quasi-regulatory bodies, such as the Flavor and Extract Manufacturers Association, an organization recognized by the Food and Drug Administration for its expertise concerning flavoring compounds. Many of the ingredients are used in other consumer products, such as cosmetics.

In addition, many of the ingredients are approved for use in tobacco products by regulatory authorities in other countries. For example, the Independent Scientific Committee on Smoking and Health in Great Britain publishes a list, commonly referred to as the Hunter-Frogett List, of ingredients that are approved for use in cigarettes. Germany also approves cigarette ingredients.

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Internal Review of Ingredients
by the Tobacco Industry

I also would like to describe briefly the steps that the tobacco industry has taken to insure that only proper ingredients are used. Ingredients have been of interest to regulatory authorities since the early 1980's, but they have been of interest to cigarette manufacturers far longer. Each company has had its own review mechanisms for ingredients, and each has carefully selected the ingredients it uses. These decisions are made by each company individually, of course, since the identity of ingredients is an important trade secret. However, since the passage of the Comprehensive Smoking Education Act of 1984, the companies have systematized their review of the use of ingredients.

Specifically, the companies have established a panel of scientists that considers safety and usage questions with respect to ingredients. This panel has carefully reviewed each ingredient and has concluded that none of them raises health concerns. This conclusion is based upon the available scientific evidence for specific ingredients, including information from the public literature and information developed by the companies. The companies have considerable scientific resources, and have utilized those resources where necessary.

One beneficial feature of this review has been a reduction in the number of ingredients in use. Even though the ingredients being used do not raise safety concerns, the use of fewer rather than more ingredients facilitates the

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review process. Nearly all formulation changes resulted from the discovery that the same flavor effect could be obtained by using fewer ingredients. Many of the flavors used by the cigarette industry are purchased from independent companies that manufacture specific flavors, and those companies often mix a wide variety of ingredients to produce a particular flavor effect. Through the panel of scientists, the companies have worked to ensure that only those ingredients that are necessary to produce the desired flavors are being used.

I would be happy to answer your questions about ingredients, as would the gentlemen with me who are scientists who serve on the industry's ingredient review panel.

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